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EXAMINER

BAUGHMAN, MOLLY E

ART UNIT

PAPER NUMBER

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MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/540,311	Applicant(s) AUGUSTUS ET AL.	
	Examiner Molly E. Baughman	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) 1-15, 19-27 and 31-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-18, 28-30, and 60-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendments to claims 16-18, and 28-30 and addition of claims 60-66 in the reply filed on 6/9/08 are acknowledged.
2. Applicant's amendments to the specification, particularly, claiming priority, and correction of typographical errors are acknowledged and accepted.

Response to Arguments

3. Applicant's arguments, see pg.13, filed 6/9/08, with respect to rejection of claims 16-18 and 28-30 under 35 USC § 112, first paragraph, written description, have been fully considered and are persuasive in view of the amendments. The rejection of claims 16-18 and 28-30 has been withdrawn.
4. Applicant's arguments, see pg.15-16, filed 6/9/08, with respect to rejection of claims 16-18 and 28-30 under 35 USC § 112, second paragraph, have been fully considered and are persuasive in view of the amendments. The rejection of claims 16-18 and 28-30 has been withdrawn.
5. Applicant's arguments, see pg.14, filed 6/9/08, with respect to rejection of claims 16-18 and 28-30 (and new claims 65-66) under 35 USC § 112, first paragraph, enablement, have been fully considered but are not persuasive. Applicants argued that the data in Example 2 provides a correlation for breast cancer with the detection of an elevated expression of a gene comprising SEQ ID NO:1. Applicants further point to Table 3, stating that the data shows a clear correlation between the cancerous state and the increased copy number of TRIP13 (a gene comprising the sequence of SEQ ID

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NO:1), explaining that not all the samples show increased gene expression (i.e. normal cells do not show increased expression). This is not persuasive because the “normal” in Table 3 is not referring to normal cells, it is referring to level of amplification of gene expression (see paragraph preceding Table 3). Therefore, out of the 547 breast cancer samples, 362 actually had normal expression of TRIP13. The data in Table 2 is similar, as it shows that in tumor tissues of various stage, grade and metastases, more cases had normal copy numbers of TRIP13 than those with amplified TRIP13. Thus, it is unclear how one of skill in the art could reasonably make a conclusion that a cell is cancerous based on the detection of increased expression of TRIP13, when the data shows that TRIP13 has normal expression in most of the tumor samples.

6. Applicant's arguments, see pg.13, filed 6/9/08, with respect to rejection of claims 28-29 under 35 USC § 102 (Dai, US 2003/0224374), have been fully considered and are persuasive in view of the amendments. The rejection of claims 28-29 has been withdrawn.

7. Applicant's arguments, see pg.13, filed 6/9/08, with respect to rejection of claims 28-29 under 35 USC § 102 (Mutter, US 6,703,204), have been fully considered and are persuasive in view of the amendments. The rejection of claims 28-29 has been withdrawn.

8. Although applicant did not submitted any arguments over rejection of claims 28-29 under 35 USC § 102 (Aziz, WO/02/086443), rejection on page 21 of the Office Action dated 2/6/08, in order to expedite prosecution, it can be concluded that the applicants

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have the same arguments over Aziz as with the other references since they all teach methods relating to SEQ ID NO:7, which has been cancelled from the claim. Therefore, the rejection of claims 28-29 has been withdrawn.

New Grounds of Rejection

Claim Interpretation

Initially, it is noted that MPEP 2111 states that, " During patent examination, the pending claims must be given the broadest reasonable interpretation consistent with the specification. In re Morris, 12'7 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997); In re Prater, 415 F.2d 1393, 162 USPQ 541 (CCPA 1969)." As such, for the purposes of examination, the method of claim 60 is drawn to a method for detecting a disposition toward developing cancer comprising: (1) detecting in a sample from a patient [interpreted as any sample from any patient] increased expression of a gene corresponding to a polynucleotide comprising the nucleotide sequence of SEQ ID NO:1 or that encodes a polypeptide having the amino acid sequence of SEQ ID NO:7. Although the wherein clause (i.e. "wherein said increased expression...") is given patentable weight in the claim, the limitations only provide conclusions based on results of the method and do not provide any actual positive steps in the method.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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10. Claims 60-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 60-66 are confusing because claim 60 is drawn to a method that detects a disposition toward developing cancer by detecting in a sample from a patient increased expression of a gene relative to that of a patient without cancer, and it is unclear how one can compare such an increase in expression to that of a patient without cancer, when the sample of a patient being detected should be from a patient without cancer if one is detecting a disposition toward developing cancer. Clarification is required.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 60-62, and 64 are rejected under 35 U.S.C. 102(e) as being anticipated by Dai et al. (US 2003/0224374, filed 6/14/02, of record).

Dai et al. teach a method comprising detecting in a sample from a patient an increased expression of a gene corresponding to a polynucleotide that encodes a polypeptide having the amino acid sequence of SEQ ID NO:7. Specifically, Dai et al. teach detecting SEQ ID NO:1896, which encodes a polypeptide having the amino acid

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sequence of SEQ ID NO:7 (see also: abstract, Fig.2-4, paragraphs [0003], [0012], [0025], and Table 1 - pg.20).

It is noted that although Dai does not teach the detection of a disposition toward developing cancer, as explained above under claim interpretation, Dai satisfies the limitations of the claim by teaching the actual positive steps required by the claim, where the determinations made on the results (i.e. increased expression of the gene) are only conclusions and are not actual positive steps required in the method.

13. Claims 60-62, and 64 are rejected under 35 U.S.C. 102(e) as being anticipated by Mutter et al. (US 6,703,204, filed 7/27/01, of record).

Mutter et al. teach a method comprising detecting in a sample from a patient an increased expression of a gene corresponding to a polynucleotide that encodes a polypeptide having the amino acid sequence of SEQ ID NO:7, specifically, Mutter teaches SEQ ID NO:29 (i.e. ABK35559, and Genbank Acc.# U96131), a polynucleotide encoding the amino acid sequence of SEQ ID NO:7 (see also abstract, col.2, lines 58-67; col.3, lines 1-53).

It is noted that although Mutter does not teach the detection of a disposition toward developing cancer, as explained above under claim interpretation, Mutter satisfies the limitations of the claim by teaching the actual positive steps required by the claim, where the determinations made on the results (i.e. increased expression of the gene) are only conclusions and are not actual positive steps required in the method.

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14. Claims 60-62 are rejected under 35 U.S.C. 102(b) as being anticipated by Aziz et al. (WO 02/086443, of record).

Aziz et al. teach a method comprising detecting in a sample from a patient an increased expression of a gene corresponding to a polynucleotide that encodes a polypeptide having the amino acid sequence of SEQ ID NO:7, specifically Aziz teach SEQ ID NO: 289, which encodes a polypeptide having the amino acid sequence of SEQ ID NO:7 (see pg.4-5, 24-26; claims 1, 7 for methods of detecting).

It is noted that although Aziz does not teach the detection of a disposition toward developing cancer, as explained above under claim interpretation, Aziz satisfies the limitations of the claim by teaching the actual positive steps required by the claim, where the determinations made on the results (i.e. increased expression of the gene) are only conclusions and are not actual positive steps required in the method.

Summary

15. Claims 16-18, 28-30, and 63 are free of the prior art, but are rejected for other reasons. No prior art has been found teaching or suggesting a sequence comprising SEQ ID NO:1, or a gene corresponding to a polynucleotide comprising the nucleotide sequence of SEQ ID NO:1 (where the specification describes genes "corresponding to" such sequences as those which share at least 90% homology to such sequences). The closest art is Mintz et al. (US 20070083334), which discloses SEQ ID NO: 292,681 and is a continuation of application 10/242,799, having a priority date of 9/13/02, however, application 10/242,799 does not disclose SEQ ID NO: 292,681, and therefore does not

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constitute *prior art*. Other prior art, Mutter et al. (US 6703204), which discloses SEQ ID NO:29, and Dai et al. (US 2003/0224374, which discloses SEQ ID NO:1896, are both 83.6% homologous to SEQ ID NO:1, and therefore, do not teach a gene comprising the nucleotide sequence of SEQ ID NO:1, or a gene sharing 90% homology to a polynucleotide comprising SEQ ID NO:1.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Molly E. Baughman whose telephone number is (571)272-4434. The examiner can normally be reached on Monday-Friday 8-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kenneth R Horlick/
Primary Examiner, Art Unit 1637

/Molly E Baughman/
Examiner, Art Unit 1637